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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,225	11/26/2001	Ruoping Chen	AREN-021CIP (21.US18.CIP)	1454

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EXAMINER	
LI, RUIXIANG	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
12/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/995,225	CHEN ET AL.	
	Examiner	Art Unit	
	RUIXIANG LI	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29,42 and 44-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29,42 and 44-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/07/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

Applicants' amendment filed on 08/07/2008 has been entered. Claims 29, 42, and 44-56 are pending and under consideration.

Information Disclosure Statement

The Information Disclosure Statement submitted on 08/07/2008 has been considered by the Examiner.

Claim Rejections under 35 USC § 101 and 112, 1st paragraph

(i). 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

(ii). Claims 29, 42, and 44-56 are rejected under 35 U.S.C. 101 and 112, first paragraph because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. The basis for the rejection is set forth in the previous office action.

(iii). Response to Applicants' argument

Beginning at page 6 of Applicants response, Applicants argue that the assertion of utility in motor control is adequately specific. Applicants argue that the instant specification unequivocally states that hRUP35 is involved in motor control. Applicants argue that the

hRUP35's role in motor control was independently confirmed by post-filing date publications. At page 10, the 3rd paragraph, Applicants argue that hRUP35 has a substantial and real-word utility, for example, in identifying compounds that can be used to treat sensorimotor processing-related disorders.

Applicants' argument has been fully considered, but is not deemed to be persuasive for because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a "real world" context of use for the claimed invention which does not require further research.

In the instant case, the specification (page 19, lines 7-11) discloses: "based on the known or assumed roles/functions of the specific tissues to which the receptor is localized, the putative physiological function of the receptor can be deduced. For example and not limitation, proteins located/expressed in areas of the thalamus are associated with sensorimotor processing and arousal". In the last paragraph of the amendment to the instant specification filed on 10/30/2007, the specification states: "RUP35 was specifically expressed in the thalamus of the brain, suggesting that RUP35 may play a role in sensorimotor processing and arousal. RUP35 was also fat cells and substantia nigra of the brain". Such an asserted utility does not represent a specific and substantial utility because Applicants were merely guessing the physiological role of RUP35 based upon the known or assumed roles/functions of the specific tissues to

which the receptor is localized. There is no evidence on the prosecution record, either in the specification or in the prior art, showing that RUP35 is identified to have a specific biological function, in particular a specific motor function. Since the specification fails to disclose a specific motor function or how it affects the motor control, the asserted use in identifying compounds that can be used to treat sensorimotor processing-related disorders is not specific and substantial.

Moreover, the post-filing date publications do not substantiate Applicants' argument that RUP35 has a specific and substantial utility. Susans et al. conclude: "The presence of GPR139 in brain areas involved in motor control suggests a function as mediator in locomotors activity. Identification of a ligand or of ligands for both receptors may help to clarify their function" (page 520, end of the article). Clearly, the specific motor function of RUP 35 remains elusive. Torres et al. (Abstract #328 of the 2006 Keystone Symposium) teach the following: GPR139 knock out mice showed impairment of motor function as evaluated by using runway and open field gait analyses, retard, balance beam, and other tests. At two months of age mice showed no impairment in any of these behaviors. At five months of age the mice showed impairment in balance. Torres et al. concluded that GPR139 null mutants appeared to have a primary age-related balance deficit. However, these results were neither disclosed by Applicants or could have been predicted from Applicants' disclosure.

The information disclosed in the instant specification is preliminary at best. Clearly further research would be required to determine a specific motor control function.

Accordingly, the claimed utility is not substantial. The instant situation is analogous to what was addressed in Brenner v. Manson, 148 U.S.P.Q. 689 (Sup. Ct, 1966), where the court held that:

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification for permitting an application to engross what may prove to be a broad field", and "a patent is not a hunting license", "[it] is not a reward for the search, but compensation for its successful conclusion."

For the reasons above and the reasons set forth in the previous office action mailed on 02/07/2008, the rejections under 35 U.S.C. 101 and 112, first paragraph.

Claim Rejections under 35 USC § 112, 1st paragraph

(i). The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(ii). Claims 44-56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The rejection is maintained for the reasons set forth in the previous office action.

(iii). Response to Applicants' argument

Applicants argue that the structure/function relationship of GPCR is well known and, as such, one of skill in the art would be able to envision a large number of operable variants of hRUP35 (SEQ ID NO: 16). Applicants argue that the specification describes the structure/function relationship of GPCR in detail at page 3, line 2 to page 4, line 15, and a variety of methods for assaying GPCRs in detail at page 17, 19, and 20. Applicants argue that Exhibit shows that a search of NCBI's PubMed database reveals that there are over 2240 journal articles that have a publication date that precedes the priority date of the instant application and contain the phrase "GPCR". Applicants argue that at the priority date of the instant application, one of skill in the art would have knowledge of the atomic coordinates of at least one GPCR. Referring to Exhibits C-E, Applicants argue that at the time of filing, the structure/function relationship of many GPCRs had been investigated, and several reviews on the structure/function relationship of GPCRs had been published (see, e.g., Exhibits F-K). applicants argue that at the time of filing, one of skill in the art would have been aware of several algorithms for predicting GPCR structure(see, e.g., Exhibits I and M), and an algorithm for predicting important residues in GPCRs (See, e.g., Exhibit N), and reviews on the engineering of GPCRs by domain swapping (See. e.g., Exhibit O and P).

Applicants' argument has been fully considered, but is not deemed to be persuasive because the general teachings on the GPCR structure and functions do not provide a surrogate for specific structure/function relationship in the instant case. The specification merely discloses a single species, a constitutively active GPCR of SEQ ID NO: 16. There is no teaching regarding which 10% of the amino acids can vary from SEQ ID NO: 16 and still result in a polypeptide that still retains the recited activity. Accordingly, the specification, taken together with the pre-existing knowledge in the art of the protein mutation, fails to satisfy the written description requirement under 35 U.S.C. §112, first paragraph.

Applicants argue that the USPTO Written Description Training Materials indicate that claims recite a polypeptide having at least 85% amino acid sequence identity to a disclosed polypeptide can meet the written description requirement, even if there is little knowledge about the structure/function relationship of the polypeptide.

Applicants' argument has been fully considered, but is not deemed to be persuasive because claim 1 of Example 11 of the USPTO Written Description Training Materials does not recite any functional limitation, whereas the instant claims recite an activity "wherein said G protein-coupled receptor is capable of stimulating intracellular IP3 accumulation in a constitutive manner". If such a recited activity is removed, the written description rejection will be overcome.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/
Primary Examiner, Art Unit 1646

Ruixiang Li, Ph.D.
December 11, 2008